

Preliminary Amendment
Docket No. CJ-0776QK
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response until February 2, 2002. Therefore the accompanying Continued Prosecution Application was filed during the co-pendency of the parent application.

B. The Amendments:

The foregoing amendments to the claims are presented in response to the Examiner's comments in the Office Action dated August 2, 2001 to more clearly and distinctly claim what Applicants believe the invention to be. Applicants do not believe that the foregoing amendments add any new matter to the specification and respectfully request that these amendments be added prior to examination.

Attached hereto please find a "Marked Up Version of the Claims" and a "Clean Version of the Claims as Amended."

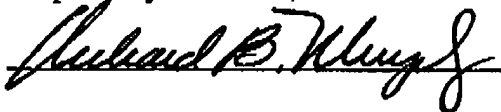
Conclusion:

Applicants believe that the claims as amended are free of the prior art and respectfully request favorable consideration thereof and that this application be passed to issuance without further delay.

Canji, Inc.
3525 John Hopkins Court
San Diego, CA 92121
Telephone: 858-646-5955
Facsimile: 858-452-4945

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Respectfully submitted,



Richard B. Murphy
Attorney for Applicants
Registration No. 35,296

Marked Up Version of the Claims

1. A method for ~~treating a patient suffering from a disease amenable to treatment by~~ of expressing an interferon-alpha polypeptide in a cell ~~by administering~~ contacting said cell with ~~into a tissue of interest of said patient~~ a recombinant viral vector comprising a nucleic acid segment encoding an interferon- α polypeptide lacking a secretion leader sequence, the nucleic acid segment being operatively linked to a promoter having specificity for the tissue of interest, wherein the interferon- α polypeptide is expressed in active form in the ~~cell-tissue of interest in~~ the patient.

2. The method of claim 1, wherein the interferon- α polypeptide is interferon- α 2b.

3. The method of claim 2, wherein the promoter having specificity for the tissue of interest is a liver-specific promoter.

4. The method of claim 2, wherein the tissue comprises a liver cancer cell.

~~6. The method of claim 5 wherein the vector is a viral vector.~~

7. The method of claim 6 3 wherein the vector is an adenoviral vector.

8. The method of claim 7 wherein the adenoviral vector is replication deficient

9. The method of claim 7 wherein the adenoviral vector is replication competent.

~~13. A method for expressing interferon α levels in a tissue of interest in a patient comprising introducing into the tissue of interest a viral vector comprising a nucleic acid segment encoding an interferon α polypeptide, the nucleic acid segment being operatively linked to a promoter having specificity for the tissue of interest, wherein the interferon α polypeptide is expressed at a therapeutically effective level in the tissue of interest in the patient.~~

~~14. The method of claim 13 wherein the wherein the nucleic acid segment encoding an interferon α polypeptide is operatively linked to nucleic acid encoding an interferon α secretion leader.~~

~~15. The method of claim 14, wherein the interferon α is interferon α 2b.~~

~~16. The method of claim 15, wherein the vector is an adenovirus vector.~~

Marked Up Version of the Claims (continued)

- ~~17. The method of claim 16, wherein the promoter is a liver-specific promoter.~~
19. A recombinant vector comprising a nucleic acid segment encoding an interferon- α polypeptide, the nucleic acid segment being operatively linked to a promoter specific for a tissue of interest, wherein the nucleic acid segment encoding the interferon- α polypeptide lacks a secretion leader sequence.
20. The vector of claim 19, wherein the interferon- α polypeptide is interferon- α 2b.
21. The vector of claim 19, wherein the interferon- α polypeptide is interferon- α 2- α 1.
22. The vector of claim 19, wherein the interferon- α polypeptide is a consensus interferon- α polypeptide.
23. The vector of claim 20, wherein the promoter is a liver specific promoter.
24. The vector of claim 20, wherein the promoter is the AFP promoter.
25. The vector of claim 24 wherein the vector is an adenoviral vector.
26. The vector of claim 25 wherein the adenoviral vector is replication deficient.
27. The vector of claim 26 which is rAdNSI- α 2b.
28. The vector of claim 25 wherein the adenoviral vector is replication competent.
29. The vector of claim 28 wherein the endogenous adenoviral E1 promoter is replaced with the AFP promoter.
30. A pharmaceutical formulation comprising a recombinant vector comprising a nucleic acid segment encoding an interferon- α polypeptide, the nucleic acid segment being operatively linked to a promoter specific for a tissue of interest, wherein the nucleic acid segment encoding the interferon- α polypeptide lacks a secretion leader sequence.
31. The formulation of claim 30 wherein the interferon- α polypeptide is interferon- α 2b.
32. The formulation of claim 31 wherein the vector is an adenoviral vector.

Marked Up Version of the Claims (continued)

33. The formulation of claim 32 further comprising a delivery enhancing agent.

34. A method of ~~treating~~ killing a hepatocellular carcinoma cell in a mammalian subject suffering therefrom by contacting said hepatocellular carcinoma cell with the administration of a pharmaceutical formulation comprising a recombinant vector comprising a nucleic acid segment encoding an interferon- α polypeptide, the nucleic acid segment being operatively linked to a promoter specific for a tissue of interest, wherein the nucleic acid segment encoding the interferon- α polypeptide lacks a secretion leader sequence.

~~35. The method of claim 34 wherein the pharmaceutical formulation is administered via the intrahepatic artery.~~

36. The method of claim ~~35~~ 34 wherein ~~the mammalian subject is a human being and~~ the interferon- α polypeptide is human interferon- α 2b.

37. The method of claim 36 wherein the vector is a recombinant adenoviral vector.

38. The method of claim 37 wherein the adenoviral vector is replication deficient.

39. The method of claim 38 wherein the adenoviral vector is rAdNSI α 2b.